REMARKS/ARGUMENTS

Claims 1-16, 20-22, 26, 64-65, and 67-78 are pending in the present application and remain rejected.

Telephonic Interview Summary

In two telephonic interviews on June 25, 2003, Applicants' representative Melissa L. Sistrunk discussed the outstanding rejections with Supervisory Patent Examiner Corrine McDermott. Issues discussed included removal of finality of the prior Office Action (mailed February 20, 2003) and removal of the rejection under 35 U.S.C. §102(b) in view of Black. Upon reviewing the file, discussing the issues with Ms. Sistrunk, and conferring with Examiner Pellegrino, it is Applicants' understanding from Examiner McDermott that the Black reference is removed as a rejection under 35 U.S.C. §102(b) and that the finality of the prior Office Action is also removed.

Examiner McDermott expressed concerns about Applicants' previous amendments to Claim 1 from "at least four" extremities to "no more than six" extremities, particularly regarding specification support and anticipation by Black. Claim 1 is amended herein without prejudice and without acquiescence to address these concerns, and support for the amendment is found in the original claims and throughout the specification, such as on Page 5, Lines 21-22.

Applicants thank both Examiners for their time and consideration.

Issues under 35 U.S.C. §103(a)

- Claims 5, 6, 10-13, 22 and 68 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black et al. (U.S. Patent No. 5,676,700; "Black") in view of Chen et al. (U.S. Patent No. 6,180,606; "Chen").

- Claims 5-8, 71, and 72 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Barralet (Biomaterials, 1993; "Barralet").

- Claims 14-16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Kondo et al. (JP 171546; "Kondo").

- Claims 2, 3, 73, 74, and 78 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Sheppard et al. (WO 94/08912; "Sheppard").

Claim 65 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black. Applicants respectfully disagree with all of these rejections. Applicants respectfully assert that the cited claims are not obvious in light of Black by itself or in combination with any of the other references.

Applicants note that, as currently agreed to by the Examiners, Black does not teach the element of "circular cross-section". Black by itself or in combination with other references fails to contain or suggest all of the elements of the pending claims. That is, as stated above, Black fails to teach or suggest having a circular cross-sectional configuration. To establish a *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981,180 USPQ 580 (CCPA 1974). In light of this criteria, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. §103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

Furthermore, Applicants assert that Black teaches away from the present invention, and therefore any combination of references with Black would also teach away from the present invention. Black teaches away from the circular transverse configuration by teaching the oval cross-section configuration. That is, Black clearly demonstrates the oval embodiment (col. 2, lines 57-67; FIG. 2; FIG. 7) and moreover states that at least in part that there are advantages of having an oval cross-sectional configuration (col. 3, lines 33-38), which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner suggested.

Applicants strongly assert that Black **as a whole** teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, ***including portions that would lead away*** from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). The oval cross-sectional shape of the Black structural elements and the indication that they are preferred and confer an advantage to the invention would, therefore, teach away from the circular cross-sectional configuration of the present invention. Thus, Applicants assert that Black teaches away from the present invention, indicating that the pending claims are, in fact, not obvious.

Furthermore, in the teleconference of June 25, 2003, Examiner McDermott suggested that the circular cross-section would be an obvious matter of design choice in view of the

oval cross-section of Black. Applicants respectfully assert that not only does Black teach away from the invention, but it is also not an obvious matter of design choice for the present invention in particular to select a circular cross-section in light of the oval cross-section of Black. The nature of the invention is to provide a bone graft substitute having both porosity and interlocking capabilities with other particles and, as stated in the accompanying 37 C.F.R. §1.132 Declaration of skilled artisan and inventor Michael B. Cooper, it is not an obvious matter of design choice to pick a circular cross-section in view of an oval cross-section. Mr. Cooper describes that the differences in shape between the oval and the circle cross-section convey dissimilar functional output of the particles in an array of particles, such differences related at least to porosity and tensile strength. These differences in functionality indicate that the two designs are not interchangeable, and therefore they cannot be obvious substitutable design choices.

Therefore, Applicants assert that all of the 35 U.S.C. § 103 rejections over Black are improper, and Applicants respectfully request that the rejections be removed.

Thus, the improper rejection of Black indicates that any combinatory rejections with other references are also improper, and Applicants respectfully request their removal. If Black teaches away from the present invention in teaching a design choice that does not render Applicant's invention obvious, then the combination of references also teach away from the invention. Thus, regarding the rejection over Black in view of Chen, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 2, Black fails to teach the claimed materials for the particles or composite materials. In addition, even adding Chen to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Chen to achieve Applicants' claimed invention, and Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Barralet, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach ceramic as gypsum or the array to have a porosity between about 40%-80%. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Barralet to achieve Applicants' claimed invention. In addition, even adding Barralet to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Kondo, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach the particle diameter being in the range of about 6mm. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Kondo to achieve Applicants' claimed invention. In addition, even adding Kondo to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Sheppard, Applicants assert that in addition to Black teaching away from the invention Sheppard also teaches away from the present invention, and therefore the combination of these references could not be obvious As acknowledged by the Examiner in a previous Action, Sheppard does not disclose a circular transverse cross-section configuration. In fact, Sheppard teaches away from the circular transverse configuration by teaching the square cross-section configuration. That is, Sheppard compares the advantages of a square cross-section over a circular cross-section, which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner contends. On Page 12, L33-34, Sheppard states: "...(3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point based coordination of spherical and random shapes..."

In addition to teaching away from the circular cross-section of Applicants' invention, the nature of Sheppard is a clear departure from the present invention, which would lead a skilled artisan in the field in a dissimilar direction. Applicants remind the Examiner about the previously filed Declaration Under 37 C.F.R. §1.132 of Dr. Ed Margerrison.

Applicants reiterate that Sheppard adumbrates on Page 12, Lines 13-19 that there may be embodiments where the aggregates are not packed into a "zero matrix", but the majority of Sheppard does, in fact, teach that the design of the arms in Figures 5 and 6 is to increase the strength by nesting tightly and providing 0% void volume. Furthermore, the essence of the entire reference teaches that the purpose of the aggregate or array of particles as per Figures 5 and 6 is to increase the strength of a composite material with the array being surrounded by a matrix material.

Sheppard teaches that the composite is likely to have an increased strength and fracture toughness compared with other means of reinforcing composite structures. The array

as shown in Figures 5 and 6 has essentially no open porosity within the structure, owing to the extremely highly reticulated structure that the "StarJack" shape gives. That is, it is mentioned that the arrangement described in Sheppard can often be achieved by mixing a number of those granules and applying vibration through *e.g.* mechanical or ultrasound means. With minimal vibrational forces, the particles of Sheppard regularly pack, and the circular cross-section of the particles of the present invention would not allow this. In fact, the advantage of the circular cross-section of the present invention is to reduce the potential for forming this reticulated structure so that a number of the individual granules together will retain an open interconnected porosity. The shape of the Sheppard granules described in the vast majority of the reference would, therefore, teach away from the configuration of the present invention.

For example, on Page 7, Line 1 Sheppard states, "One aspect of the present invention is an aggregate having a unique three-dimensional shape theoretically capable of packing to 100% density without any void volume....." The particles of the present invention cannot pack to 100% density, nor would such density be desirable for treating a bone deficiency (an element of Claim 1).

Also, on Page 12, Line 2 it states, "As shown by Figs. 4-6, this property permits the aggregates to be arranged in a nesting configuration, wherein faces of one aggregate are disposed adjacent faces of neighboring aggregates in a regular array.

Applicants expand the above citation of the following passage on Page 12 from Sheppard:

"We believe the Starjack, Tetratwin and Tetrastar represent novel classes of aggregate shapes with reticulate geometries marked by, for example:

(1) The ability of same-class components of equivalent volume to ***nest*** uniformly;

(2) Improved architectural properties of the nesting pattern itself (reticulate matrix), which may be varied in its thickness dimension in accordance with application demands;

(3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point-based coordination of spherical and random shapes or the line-to-line based coordination of fibrous reinforcements;

(4) Substantially increased potential for crack path tortuosity.... (emphasis added)"

As described in the previously filed affidavit, Applicants assert that one skilled in the art would not recognize that the array of particles of the present invention illustrated in Figure 2 in the instant specification are in a "nested" array. Instead, one skilled in the art interprets the term "nested" to mean "to pack compactly together," and in the context of the teachings of Sheppard for flat surfaces of the arms in a "plane-based coordination", the packing would be so compact as to teach away from the bone deficiency-treating configuration of the array as taught by the Applicants.

Thus, Applicants reiterate that for multiple reasons Sheppard teaches away from the present invention. Therefore, the Black reference, the Sheppard reference and the combination of Sheppard with Black all teach away from Applicants' invention, and this indicates that the pending claims are, in fact, not obvious in light of these references. Moreover, even adding Sheppard to Black does not provide or suggest the missing element in Black of circular cross-section.

Applicants also submit that the rejections under 35 U.S.C. §103(a) for Black alone and in combination respectively with Chen, Barralet, Kondo, and Sheppard are each an application of an "obvious to try" standard in the field of shaped bone particles. For Black, the reference teaches a oval cross-sectional configuration and the advantages therewith, and although Applicants strongly assert this teaches away from the present invention, Applicants also suggest the Examiner is improperly citing an obviousness rejection wherein the rejection is more accurately an "obvious to try" rejection. The "obvious to try" standard has been held to constitute an improper ground for a 35 U.S.C. § 103 rejection. *In re O'Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An "obvious-to-try" situation exists when a general disclosure may pique an inventor's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Similarly, Black does not teach Applicants invention, and although the Examiner alleges the particles in Black are obvious, Applicants assert the oval cross-sectional configuration of the particles teach away from the present invention, and the rejection is in fact an "obvious to try" rejection.

In summary, the Black reference does not teach Applicants' invention and Applicants'

invention is not obvious because Black teaches away from the invention. Applicants' design is also not an obvious design choice in light of Black, as explained by inventor and skilled artisan Michael B. Cooper in the accompanying 37 CFR §1.132 Declaration.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01952US0 from which the undersigned is authorized to draw.

Dated:

Respectfully submitted,

By _____

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be tested in determining one that is useful for both interlocking and porosity (note the Sheppard reference even utilizes a square cross-section, although it likely provides insufficient porosity for bone ingrowth). Particularly regarding cross-sections related to circles and ovals, there is nothing obvious or intuitive that an oval cross-section as a design for an interlocking particle that also allows porosity would indicate a circular cross-section would perform similarly.

Not only is there not an obvious matter of cross-sectional design choice to select a circle in view of an oval, but a skilled artisan from reading Black would likely refrain from considering a circular cross-section design, given that the reference refers to advantages of having an oval cross-sectional configuration (col. 3, lines 33-38). Because of this teaching, a skilled artisan in this field would not necessarily presume a circular cross-section would have the same advantage and, furthermore, would likely avoid the labor and expense to perfect its design and manufacture, given the acknowledged advantage of the oval cross-section.

Black states (col. 3, lines 23-42):

> The tightly meshed array 42 of interlocked structural elements 10 establishes a structural matrix of sound mechanical cohesive characteristics for attaining desirable mechanical properties, while providing an osteoconductive or osteoinductive matrix for the ingrowth of natural bone. Thus, the interengaged structural elements 10 are meshed tightly enough and are interlocked to provide a structural matrix which tends to resist shear stress in essentially all directions within the array 42, while the nature of the material of the structural elements 10 allows for the ingrowth of natural bone. The oval cross-sectional configuration of the posts 12, and the tapering of the posts 12 along the length L thereof, enhance the ability of the posts 12 to enter the inter-post spaces 16 and attain meshing and interlocking of the structural elements 10 in the desired tight relationship. The mechanical strength of the matrix thus provided by the array 42 is sufficient to enable load-bearing, even upon initial implant of the femoral implant 32, whether utilized alone to fill a void such as cavity 30, or in combination with autologous bone or autologous blood.

Thus, Black teaches that its particles have similar advantages to those demonstrated by our particles. If a skilled artisan is taught by Black that a particle with an oval cross-section has the advantage of providing both porosity and an interlocking shape, then why would a skilled artisan presume the same would be provided by a shape lacking the contour of an oval (*e.g.*

not having two longer "sides" of its contour), particularly when Black asserts: "[the] oval cross-sectional configuration of the posts...enhance[s] the ability of the posts...to enter the inter-post spaces...and attain meshing and interlocking"?

An oval, in the context of the present invention, is not necessarily similar *in function* to a circle. An oval shape in particular would not intuitively teach similar advantages for a circular cross-section. For example, the longer "side" of the oval contour can lie flat against the longer side of the oval contour of an adjacent particle for one pair of adjacent particles in an array, whereas the longer side of the oval contour of one particle can lie against the shorter "side" for another pair of adjacent particles in the same array. This configuration would thereby impart a somewhat unpredictable porosity for an array that is not palpable in function with an array from particles having circular cross-sections.

As stated, bone graft substitutes are used in the art as bone void fillers to preferably provide an environment having consistent porosity and interlocking for any void, void volume, or shape of void. It is extremely important to recognize that it is not intuitive what geometry would provide such an environment. It is not necessarily true that the configuration of particles having oval cross-sections would provide consistent interlocking and porosity, and in the case of oval cross-sections it is unclear that the dissimilar contours for the "sides" of the oval would provide consistency. It is simply not obvious what shapes would meet these conditions, including whether circular cross-sections would be satisfactory.

The circular cross-section of the extremities of the particle are certainly not an obvious matter of design choice. The design choice of the circular cross-section compared to the oval should not function in the same manner for their intended purpose, given their dissimilar contours. The circular cross-sectional area has proportionately the same forces in any direction across the cross-section, whereas in an oval cross-section the forces are not. For example, the forces across the different amounts of material (depending on the direction) of the cross-section in the oval-based arm provides weaker points in terms of tensile strength and so forth. The inherent functional differences mean that the design of the oval is not interchangeable with the design of the circle. The substitution of a circle for an oval cross-section is not a trivial substitution, and in the design of the particles of the present invention we have discovered that the circular cross-sectional properties are critical to how it functions. It would not be a mere design choice to exchange circle for oval.

Thus, I hereby state that in view of the above discussion the design of the particle of the Black reference does not render our particle obvious and, furthermore, that in teaching away from our invention our particle can not be obvious in view of Black.